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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/688,791   | 10/17/2003  | Jay S. Teich         | THI-002             | 9704             |
| 51414  | 7590        | 03/13/2006           | EXAMINER            |                  |
| GOODWIN PROCTER LLP<br>PATENT ADMINISTRATOR<br>EXCHANGE PLACE<br>BOSTON, MA 02109-2881 |             |                      | BULL, CHRISTOPHER   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1655                |                  |

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/688,791 | <b>Applicant(s)</b><br>TEICH ET AL. |  |
|                              | <b>Examiner</b><br>Christopher Bull  | <b>Art Unit</b><br>1655             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-80 are pending.

#### ***Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, drawn to a Method of analyzing cells disposed in a media within a vessel by reducing the media volume and analyzing a constituent within the reduced volume, classified in class 435, subclass 29.
- II. Claims 40-54, drawn to an Apparatus for analyzing cells comprising a stage, a plunger, and a sensor, classified in class 435, subclass 288.7.
- III. Claims 55-68, drawn to a Multiwell Plate for holding media and cells, classified in class 435, subclass 288.4.
- IV. Claims 69-80, drawn to a Barrier mating with a vessel to create a reduced volume for analysis of cells disposed in a media, classified in class 435, subclass 287.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I (Method) and II-IV are related as process and various kinds of apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of Group I may be practiced without any of the apparatus in Groups II-IV. For example, the method

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of analyzing constituents related to cells by reducing the volume of a culture of cells may easily be accomplished in a pressurized ultrafiltration cell, without either the piston required by Group II or the barrier of Group IV, by placing the sensor in the permeate that appears outside the membrane or within the reduced volume. Claim 39 of Group I does not require the barrier of Group IV to provide the step of sealing the vessel. Further, no claim in Group I requires use of a multiwell plate as in Group III, so the invention of Group I may be practiced with the above mentioned ultrafiltration cell. Therefore Group I is distinct from the other groups.

Inventions II (Apparatus) and III (Multiwell Plate) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination is claimed broadly and the subcombination is claimed with further particulars. None of the claims in Group II require the "seating surface adapted for receiving a barrier" required of Group III. Claim 43 in Group II requires only a step in a well of a multiwell plate, which is broader than Claim 60 of Group III wherein a "seating surfaces of the wells each comprise a step disposed about an inner periphery of a well". The subcombination has separate utility such as any multiwell plate may be used for.

Inventions II (Apparatus) and IV (Barrier) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the

combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination is claimed broadly and the subcombination is claimed specifically. Group II requires of a barrier only that it be "adapted for insertion into the vessel by relative movement of the stage and the plunger" (i.e., only that it fits into, but need not touch, seal or mate). The subcombination of Group IV is required to have "a barrier surface for mating with a first surface of the vessel to create a reduced volume". The subcombination has separate utility such as performing the function of a rubber stopper.

Inventions III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, the subcombination do not overlap in scope and both have separate utility such as general multiwell plates or stoppers, as discussed above. See MPEP § 806.05(d).

The inventions above are independent or distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search: Group I requires searching for analysis of some media constituent in a trapped volume of a cell culture, including membrane permeates. Group II requires

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searching for sensors, as well as for moveable stages and plungers. Group III requires searching for multiwell plates having seating surfaces. Group IV requires searching for insertable devices reducing volume and allowing analysis of some cell related constituent. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of one Group from among the **four** inventions, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention.

### ***Election of Species***

This application contains claims directed to the following eleven patentably

| distinct types of species: | <u>Type</u> , as listed in | <u>Claim(s)</u> | of | <u>Group(s)</u> |
|----------------------------|----------------------------|-----------------|----|-----------------|
| Type of Cell               | A                          | 8               |    | I               |
| Type of Constituent        | B                          | 12              |    | I               |
| Type of Dissolved Gas      | C                          | 13              |    | I               |
| Type of Cation             | D                          | 14              |    | I               |

|                              |   |                     |         |
|------------------------------|---|---------------------|---------|
| Type of Protein              | E | 15                  | I       |
| Type of Substrate            | F | 16                  | I       |
| Type of Sensor               | G | 24, 45              | I, II   |
| Type of Parameter            | H | 25                  | I       |
| Type of Altered Environment. | I | 35                  | I       |
| Type of Seating Surface      | J | 56, 70              | III, IV |
| Type of Further Method Step  | K | 2, 26-27, 34, 36-39 | I       |
| Type of Constituent Analysis | L | 19-23 and 25        | I       |

The species within each of these eleven types are independent or distinct because the members of each Type do not share a common structure or property. In addition, the searches required would not be coextensive and would constitute a distinct burden, given the multiplicity of potential combinations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each Type of Species A-L, for prosecution on the merits, to which the various claims shall be restricted if their generic claims are not finally held to be allowable. Currently, claims 1, 12, 23, 40, 55 and 69 may be generic to the eleven Types of Species.

Applicant is advised that, to be complete, a reply to this requirement must include an identification of the species that is elected consonant with this requirement, even though the requirement be traversed (37 CFR 1.143), and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Bull whose telephone number is (571) 272-1327. The examiner can normally be reached on 7:30-4.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Bull  
Patent Examiner  
Art Unit 1655

cb

  
TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER